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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,460	09/19/2003	Georges Freyssinet	A335992-PCT-USA-A(072667.	6831
21003	7590	03/21/2006	EXAMINER	
BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			CHISM, BILLY D	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,460

Applicant(s)

FREYSSINET ET AL.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-11, drawn to modified Cry protein, classified in class/subclass 514/2+, for example.
 - II. Claims 12-21, drawn to methods of making Cry protein, classified in class 530, subclass 350, for example.
 - III. Claims 22-31, 37-38 and 39-40, drawn to DNA, expression vector, host cells and transformed host organism, classified in class 435, subclass 69.1, for example.
 - IV. Claims 32-35, drawn to methods of making Cry protein, classified in class 800, subclass 4+, for example.
 - V. Claim 36, drawn to antibodies, classified in class 424, subclass 130.1.
2. The inventions are distinct or independent, each from the other because:
3. Group I, is generic to a plurality of disclosed patentably distinct species comprising all modified Cry proteins. If Applicant elects Group I, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.
4. Group II, is generic to a plurality of disclosed patentably distinct species comprising all methods of making each modified Cry protein. If Applicant elects Group II, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.
5. Group III, is generic to a plurality of disclosed patentably distinct species comprising nucleic acid sequences, and vectors, host cells and transformed organisms thereof, for all

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encoding all modified Cry protein. If Applicant elects Group III, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

6. Group IV, is generic to a plurality of disclosed patentably distinct species comprising method of using nucleic acid sequences, and vectors, host cells and transformed organisms thereof, encoding all modified Cry protein. If Applicant elects Group IV, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

7. Group V, is generic to a plurality of disclosed patentably distinct species comprising monoclonal antibodies to all modified Cry proteins and species comprising polyclonal antibodies to all modified Cry proteins. If Applicants elect Group V, Applicants are required under 35 U.S.C. 121 to elect a single disclosed species, eve though this requirement is traversed.

8. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Groups I, II and IV are related as process of making (Groups II and IV) and product made (Group I). The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by either of the methods of Groups II and IV, and therefore the inventions are distinct as being drawn to product and methods of making product.

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Additionally, the methods of Groups II and IV are independent in that they require different steps and components for the production of the modified Cry proteins.

10. Groups I and III are distinct inventions. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

11. Groups I and V are structurally and functionally different biological compounds and are therefore independent inventions.

12. Groups II and III are independent inventions wherein the method steps of Group II neither require nor make the apparatus of Group III; therefore, the inventions are independent.

13. Group III is related to the method of Group IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid Group III may be used in hybridization assays, PCR or sequence reaction.

14. Groups III and V are structurally and functionally different biological compounds, being made by different processes and having different biological affects; therefore are independent inventions.

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15. Group V is neither made by nor does it use the method steps of the process Groups II and IV; therefore, the Groups V and II-IV are independent inventions.

16. Because these inventions are distinct for the reasons given above and the search required for any of Groups I-V would not necessarily be inclusive of the other Group or Groups, and because the Groups I-V are classified differently, restriction for examination purposes as indicated is proper.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

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patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more

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information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDC



B. DELL CHISM
PATENT EXAMINER